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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Splicants : Timothy Norris et al.

Serial No. : 09/711,272 Group Art Unit: 1624

Filed: November 9, 2000 Examiner: T. McKenzie

For : STABLE POLYMORPH ON N-(3-ETHYNYLPHENYL)-6,

7-BIS (2-METHOXYETHOXY)-4-QUINAZOLINAMINE HYDROCHLORIDE, METHODS OF PRODUCTION, AND

PHARMACEUTICAL USES THEREOF

1185 Avenue of the Americas

New York, New York 10036

September 30, 2003

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

## SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

In accordance with their duty of disclosure under 37 C.F.R. §1.56, applicants would like to direct the Examiner's attention to the following documents which are listed on Form PTO-1449 (Exhibit A) and are also listed below. A copy of the references listed below as items 1-8 are attached hereto as Exhibits 1-8.

This Information Disclosure Statement is being submitted pursuant to 37 C.F.R. §1.97(b)(3) before the mailing of a first Office Action on the merits. Thus, this Information Disclosure Statement should be entered and considered.

- U.S. Application Publication No. 2002/0061304 (Miller et al.) published May 23, 2002 (Exhibit 1);
- PCT International Application Publication No. WO 96/25422, published August 22, 1996 (Exhibit 2);

Applicants: Timothy Norris et al.

Serial No.: 10/711,272

Filed: November 9, 2000

Page 2

3. PCT International Application Publication No. WO 01/70255, published September 27, 2001 (Exhibit 3);

- Driscoll D. et al., "Effect of Epidermal Growth Factor Receptor Tyrosine Kinase Inhibitor PD183805 on Vascular Endothelial Growth Factor Secretion from Several Tumor Models" (1999) XP-001014746 (Abstract only) (Exhibit 4)
- 5. Ishiwata T. et al., "Characterization of Keratinocyte Growth Factor and Receptor Expression in Human Pancreatic Cancer" (1998) American Journal of Pathology 153(1): 213-222 (Exhibit 5);
- 6. Liu N. et al., "Comparative Phenotypic Studies of Duct Epithelial Cell Lines Derived from Normal Human Pancreas and Pancreatic Carcinoma" (1998) American Journal of Pathology 153(1) 263-269 (Exhibit 6);
- 7. Watanabe M. et al., "Overexpression of Keratinocyte Growth Factor in Cancer Cells and Enterochromaffin Cells in Human Colorectal Cancer" (2000) Pathology International 50:363-372 (Exhibit 7) and
- 8. Woodburn J.R. et al., "ZD1839, An Epidermal Growth Factor Tyrosine Kinase Inhibitor Selected for Clinical Development" (1997) XP-001009911 (Abstract only) (Exhibit 8).

Applicants request that the Examiner review the references and make them of record in the subject application.

Applicants: Timothy Norris et al.

Serial No.: 10/711,272

Filed: November 9, 2000

Page 3

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee is deemed necessary in connection with the filing of this Supplemental Information Disclosure Statement. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:

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Serial No. Porm.PTO-1449 Atty. Docket No. U.S. Department of Commerce 62814-A/JPW/GJG/JBC 09/711,272 **Patent and Trademark Office** Applicants: Timothy Norris et al. INFORMATION DISCLOSURE CITATION Filing Date Group (Use several sheets if necessary) 1624 November 9, 2000 **U.S. PATENT DOCUMENTS** Class Subclass Filing Date Date Document Number Name if Appropriate Initial Miller et al. 20 02 00 61 5/23/02 (Exhibit 1); FOREIGN PATENT DOCUMENTS Translation Subclass Document Number Date Country Class Yes No 8/22/96 PCT (Exhibit 2); WO |9 wo o 9/27/01 PCT (Exhibit 3); OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) Driscoll D. et al., "Effect of Epidermal Growth Factor Receptor Tyrosine Kinase Inhibitor PD183805 on Vascular Endothelial Growth Factor Secretion from Several Tumor Models" (1999) XP-001014746 (Abstract only) (Exhibit 4) Ishiwata T. et al., "Characterization of Keratinocyte Growth Factor and Receptor Expression in Human Pancreatic Cancer" (1998) American Journal of Pathology 153(1): 213-222 (Exhibit 5); Liu N. et al., "Comparative Phenotypic Studies of Duct Epithelial Cell Lines Derived from Normal Human Pancreas and Pancreatic Carcinoma" (1998) American Journal of Pathology 153(1) 263-269 (Exhibit 6): Watanabe M. et al., "Overexpression of Keratinocyte Growth Factor in Cancer Cells and Enterochromaffin Cells in Human Colorectal Cancer: (2000) Pathology International 50:363-372 (Exhibit 7) and Woodburn J.R. et al., "ZD1839, An Epidermal Growth Factor Tyrosine Kinase Inhibitor Selected for Clinical Development" (1997) XP-001009911 (Abstract only) (Exhibit 8). DATE CONSIDERED EXAMINER \*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in

conformance and not considered. Include copy of this form with next communication to applicant.

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Serial No.: 09/711,272 Filed: November 9, 2000

Exhibit A